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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,930	02/14/2002	Gary Taurick	N1305-023	5325

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JONDLE & ASSOCIATES P.C.
9085 EAST MINERAL CIRCLE
SUITE 200
CENTENNIAL, CO 80112

EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,930

Applicant(s)

TAURICK, GARY

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-10 and 33-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5,7,9,10 and 35-40 is/are allowed.
- 6) ☒ Claim(s) 8, 33-34, 41-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1--5, 7-10 and 33-42 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment and Arguments

3. The objection to claims 1, 7, 9 and 18 for the inclusion of a blank line where the ATCC Accession number should be is WITHDRAWN in light of Applicant's response.
4. The rejection of claims 11-13, 15-17 and 19-32 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Walters et al (1997, HortScience 32:1301-1303) is WITHDRAWN in light of their cancellation.
5. The rejection of claims 11-13, 15-17 and 19-32 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Wehner (1998, Hortscience 33:168-170) is WITHDRAWN in light of their cancellation.
6. The rejection of claims 1-32, as it applies to the instant claims, under 35 USC 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention has been withdrawn in view of Applicant's assertion that the deposit information for soybean SD93038 will be completed when the case is in condition for allowance.

Claim Objections

7. Claim 8 remains objected to because of the following informalities:

Claim 8 lacks a period at the end of the claim and there should be an --and-- after "cotyledons," in line 4.

Claim Rejections - 35 USC § 112

8. Claims 33-34 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 29 January 2003, as applied to claims 6, 11-13, 15-17 and 19-32, due to amendment of the claims. Applicant's arguments filed 29 May 2003 have been fully considered but they are not persuasive.

The claims are drawn to a method of making transgenic plants by transformation with a gene conferring sex determination, parthenocarpy or bitterness, and plants thereby produced. The claims are also drawn to a method of making single gene converted plants that comprise a gene conferring herbicide resistance, insect resistance, resistance to bacterial disease, resistance to fungal disease, resistance to viral disease, sex determination, parthenocarpy or bitterness, and plants thereby produced.

The specification, in contrast does not describe the sequence of genes conferring sex determination, parthenocarpy or bitterness. The specification also does not describe the plants used in the single gene conversion method.

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Because the sequences are not described, the method of using the sequences to produce plants with sex determination, parthenocarpy or bitterness is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

and at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Applicant urges that claims 6, 11-13, 15-17 and 19-32 have been canceled (response pg

2). This is not found persuasive for the reasons detailed above.

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9. Claims 33-34 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is modified from the rejection set forth in the Office action mailed 29 January 2003, as applied to claims 6 and 29-31, due to amendment of the claims. Applicant's arguments filed 29 May 2003 have been fully considered but they are not persuasive.

The claims are drawn to a method of making transgenic plants by transformation with a gene conferring sex determination, parthenocarp or bitterness, and plants thereby produced. The claims are also drawn to a method of making single gene converted plants that comprise a gene conferring herbicide resistance, insect resistance, resistance to bacterial disease, resistance to fungal disease, resistance to viral disease, sex determination, parthenocarp or bitterness, and plants thereby produced.

The instant specification fails to provide guidance for making a single gene conversion. No guidance is provided for introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the plants, wherein said introgression results in successful expression of the desired trait but does not interfere with the expression of the remaining traits such that essentially all of the desired morphological and physiological characteristics of the inbred are recovered in addition to the single gene (as required in the definition in ¶0033).

With respect to single gene conversions, it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant background may be introgressed into the genetic background of a different plant to confer a desired phenotype in the plant. Hunsperger et al (1996, US Patent 5,523,520) teach that introgression of a gene in one genetic background into

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any other plant of the same species, as performed by sexual hybridization, is unpredictable into producing a single gene conversion plant with a desired trait (column 3, lines 26-46). In particular, they teach that a gene conferring miniature plant stature, which was in one Petunia cultivar, does not confer the miniature phenotype when introgressed into the genome of other petunia cultivars (column 3, lines 40-41). Kraft et al (2000, Theor. Applied. Genet. 101:323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion and that such effects are unpredictably genotype specific and loci-dependent in nature (pg 323). Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials which contributes to the unpredictability of the effect. Lastly, Eshed et al (1996, Genetics 143:1807-1817) teach that in plants, epistatic genetic interactions from various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (pg 1815).

Lastly, the instant specification fails to provide guidance for the sequence of genes conferring sex determination, parthenocarpy or bitterness. The sequence of such genes is not taught in the art; the genes are only known as genetic loci.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate plants having all of the morphological and physiological characteristics of a plant produced by growing 8D-5079 seed, wherein the plants are transformed with a gene conferring sex determination, parthenocarpy or bitterness or wherein the plants comprise a single gene

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conversion that comprises a gene conferring herbicide resistance, insect resistance, resistance to bacterial disease, resistance to fungal disease, resistance to viral disease, sex determination, parthenocarpy or bitterness,

Applicant urges that Hallauer et al, not sent with the response, teach that backcrossing is an important method of breeding, and that it is sufficient for single genes (response pg 2-3).

This is not found persuasive. Hallauer et al could not be considered because it was not sent. It is noted that Kraft et al (2000, Theor. Applied. Genet. 101:323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion and that such effects are unpredictably genotype specific and loci-dependent in nature (pg 323).

Applicant urges that the specification on pg 29-30 provide guidance for genes conferring sex determination, or improved nutritional or agronomic quality (response pg 3).

This is not found persuasive. The *bi*, *Pc*, *AR*, *Cmv*, *M*, *a* and *Acr* genes listed in pg 30 have not been isolated. Thus, they cannot be used to transform a plant.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 8, 33-34 and 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The rejections are new. Dependent claims are included in all rejections.

Claim 8 is indefinite in its recitation of "the tissue is from a tissue ... hypocotyls". Not all the members of the list are tissues.

Claims 33 and 41 are indefinite in their recitation of "wherein the transgene confers a characteristic selected from ... sex determination". Sex determination is not a characteristic; however, a transgene could potentially control whether the plant is monoecious or diecious.

Conclusion

12. Claims 1-5, 7-10 and 35-40 are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
August 4, 2003



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